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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/508,635
Filing Date: May 18, 2000
Appellant(s): BALLEVRE ET AL.

Robert Barrett
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/7/06 appealing from the Office action mailed 11/15/06.

(1) Real Party in Interest.

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences.

A statement identifying any related appeals and interferences which will directly affect or be directly affected by or having a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of claims.

The statement of the status of claims contained in the brief is not correct. Claims 30, 32-35, 37-41 are pending in the application, and claims 33-34 are withdrawn from consideration.

(4) Status of Amendments After Final.

The appellant's statement of the status of amendments is correct. The amendment filed 1/9/06 was not entered.

(5) Summary of invention.

The summary of invention contained in the brief is correct, but with the exception that descriptive support for the term "internally administering" is lacking, as is descriptive support for the term "internal organ". (These two issues are discussed further below).

(6) Grounds of Rejection to be Reviewed on Appeal

Appellant's statement of the issues in the brief is no longer correct. The changes are as follows:

- The rejection of claims 30, 32, 35 and 37-41 (under 35 U.S.C. §103) as being unpatentable over Jolles (USP 4,716,151) is withdrawn.

- The rejection of claims 30, 32, 35 and 37-41 (under 35 U.S.C. §103) as being unpatentable over Nakamura (*J. Dairy Sci.* **78** (6) 1253-1257, 1995) is withdrawn.

- The rejection of claims 30, 32, 35 and 37-41 (under 35 U.S.C. §103) as being unpatentable over Masuda (*American Institute of Nutrition* **126**(12) 3063-3068, 1996) is withdrawn.

- The rejection of claim 32 (under 35 U.S.C. §103) as being unpatentable over Nakamura (*J. Dairy Sci.* **78** (6) 1253-1257, 1995) in view of Ichikawa (USP '867) is withdrawn.

- The rejection of claim 32 (under 35 U.S.C. §103) as being unpatentable over Masuda (*American Institute of Nutrition* **126**(12) 3063-3068, 1996) in view of Ichikawa (USP '867) is withdrawn.

- The rejection of claims 30, 32, 35 and 37-41 (under 35 U.S.C. §103) as being unpatentable over Ballard (USP 5,679,771) in view of Stalker (USP 5,661,123) is withdrawn.

(7) Claims Appendix

The copy of the appeals claims contained in the Appendix to the brief is correct.

(8) References Relied Upon

Gray (USP 5,723,446).

Gordon (USP 5,166,132)

Ichikawa (USP 5,071,867)

Panigrahi (USP 5,981,590)

Smith (WO 97/16460).

Stalker (USP 5,661,123)

Van Leeuwen (USP 6,001,878).

Verma (USP 6,645,942)

Atkinson (*Chronobiology International* 18 (6) 1041-53, 2001).

Bezeau (*Journal of Clinical and Experimental Neuropsychology* 23 (3) 399-406, 2001)

Bolton (*Journal of Clinical Pharmacology* 38 (5) 408-12, 1998)

Boza, Julio (*Journal of Pediatric Gastroenterology and Nutrition* **22**(2) 186-193, 1996).

Bryant (*Pediatric Allergy and Immunology* 9 (3) 108-15, 1998)

Chung (*Plastic and Reconstructive Surgery* 109 (1) 1-6, 2002)

Ludbrook (*Clinical and Experimental Pharmacology and Physiology* 28 (5-6) 488-92, 2001)

Masuda (*American Institute of Nutrition* **126**(12) 3063-3068, 1996).

Nakamura (*J. Dairy Sci.* **78** (6) 1253-1257, 1995)

Qu, Zhensheng (*Journal of Nutrition* **126**(4) 906-912, 1996)

Van Leeuwen (USP 6,001,878)

Willenheimer (*Progress in Cardiovascular Diseases* 44 (3) 155-67, 2001)

(9) Grounds of Rejection.

The following grounds of rejection are applicable to the appealed claims:

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 30 now recites that the organ for which recovery is to be promoted has to be an "internal organ". ~~As it happens,~~ There is no literal support for the term "internal organ".

Appellants are attempting to carve out a genus which was not described. Further, there

is some ambiguity regarding the dividing line between internal organs and external ones.

In addition to the foregoing, there is no description of "internal administration". It is true that on page 9, lines 6-7, the following passage is recited:

> "The nutritional formula may also be administered continuously by means of nasogastric tubes or enteral tubes...".

However, this does not provide support for "internal administration", or even parenteral administration. Nor is it clear what exactly is encompassed by "internal administration".

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to teach a skilled physiologist how to use protein hydrolyzates and amino acids to promote "recovery" of an organ. As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988), the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

As for the "nature of the invention", it is asserted in the specification (page 8, line 17+) that the disclosed protein hydrolyzates can be used to repair damage to the intestine. Also asserted (page 8, line 20+) is that the disclosed protein hydrolyzates can be used to treat Crohn's disease, diarrhea, colitis or sepsis, and further, that the disclosed protein hydrolyzates can be used to reverse damage to gut epithelial tissue that has resulted from a surgical procedure, or from any other cause. Though not specifically stated, the implication is that various diseases such as hepatitis, cirrhosis of the liver, and kidney infection can be successfully treated. Such diseases cause damage to organ tissue, and if the claimed method is to be effective, the protein hydrolyzates must be effective not only to accelerate wound healing, but overcome the pathological basis of the organ damage. Appellants have argued that while the term "recovery of an organ" is intended to encompass Crohn's disease, diarrhea, colitis and sepsis, the skilled artisan reading the specification would come to believe that hepatitis, cirrhosis of the liver, and kidney infection are all excluded. However, the reasons for such a conclusion are not provided by the specification. If "recovery of an organ" can encompass treatment of Crohn's disease, diarrhea, colitis and sepsis, it stands to reason that other diseases which affect organs would be encompassed as well. Furthermore, the skilled microbiologist would expect that many organs of the septic patient would be affected, not just the bowel.

As for the "working examples", the specification discloses results which are consistent

with the conclusion that if one administers a mixture of all 20 genetically encoded amino acids to a mammal, the relative weights of the stomach, intestine, duodenum jejunum, liver, gastrocnemius, soleus, and extensor will vary slightly if the ratio of amino acids is altered. This assertion is somewhat suspect, since no statistical analysis has been presented. For example, in the case of the duodenum, the standard deviation would not have to be high at all in order to justify the conclusion that the results are not statistically significant. Without further information as to the variability in the data (that is presented on page 17), it is not particularly meaningful. The results are also not meaningful, since the amount of lipids and minerals (see page 14) were varied simultaneously with the amino acid composition. Furthermore, the total amount of amino acids varies from ~~from~~ one feed mixture

to the next. Thus, even if it turns out that the results on page 17 are statistically significant, it has not been determined the extent to which, or even whether, the observed changes in organ weights were the result of varying the amino acid composition, rather than the lipids and minerals. It may be the case that the changes in organ weights were due to changes in the total amount of amino acids administered, rather than variations in the amino acid content. Or maybe the changes in organ weights were due to changes in differential metabolism of the peptide fragments which were produced by the different hydrolysis methods (hydrolyzate 1, hydrolyzate 2 or hydrolyzate 3). Thus, in the disclosed

experiments (specification) several different variables have been altered simultaneously, and it is impossible to determine the effects of any one of them taken alone. Furthermore, there is no control experiment. It has not been stated what the results are supposed to be relative to. If the feed compositions (feed 1 - feed 5) were given to rats which were already exhibiting a positive nitrogen balance, would there be any effect at all of the different feeds?

Even if it turns out that the results on page 17 are statistically significant, and if could be determined what the cause (among the numerous variables) of the variance in organ weights might be, the results are still not meaningful with respect to the claimed invention. The claimed invention is not drawn to a method of randomly altering the weights of selected organs. And even if the claims were drawn e.g., to a method of increasing the weight of the stomach, it is not at all clear how one would proceed. It may be true that if one uses, e.g., feed #5 rather than feed #1, one will obtain a slightly higher weight of the stomach. If it were to turn out that this difference is due to the amino acid content, rather than to the lipids and minerals (or one of the other variables), it would still not be evident how one would translate the results of feed #5 versus feed #1 into a general method of increasing stomach weight. It is not apparent which amino acids are necessary, or which are sufficient; it is not made clear what degree of hydrolysis will produce the intended results, and which will not. And even if it were true that the specification taught the skilled artisan how to increase the weight of specific organs, there is no teaching as to how that teaching

would translate into a showing of enablement for the claimed invention, which is that of using protein hydrolyzates and amino acids to promote "recovery" of an organ.

The results of a second experiment are presented on pages 21-24. What is shown here is that the rate of protein synthesis varies somewhat depending on which of the five feeds is used. The shortcomings of the experimental results described on page 17 apply here as well. First, the results are not statistically significant in the absence of further information as to the variability that is observed from one experiment to the next (for a given feed composition). Second, there are several different variables (with respect to the feed composition itself) which are altered simultaneously. And third, even if there were a clear assertion as to the specific variable that is supposed to correlate with the increased protein synthesis, and even if there were an experimental basis for such an assertion, this would have little relevance to the claimed invention, which is that of using protein hydrolyzates and amino acids to promote "recovery" of an organ. The specification has presented no evidence that any such correlation exists between rate of protein synthesis, and recovery of an organ from wounding, physical trauma, or damage from an inflammatory condition. The reality is that one cannot "predict" such "recovery" based on rates of protein synthesis.

The following references discusses the issue of statistical analysis, and more importantly the issue of artifacts or invalid conclusions that can be drawn from an inadequate experimental design, or flawed assumption:

Ludbrook (*Clinical and Experimental Pharmacology and Physiology* 28 (5-6) 488-92, 2001)

Bryant (*Pediatric Allergy and Immunology* 9 (3) 108-15, 1998)

Bezeau (*Journal of Clinical and Experimental Neuropsychology* 23 (3) 399-406, 2001)

Bolton (*Journal of Clinical Pharmacology* 38 (5) 408-12, 1998)

Willenheimer (*Progress in Cardiovascular Diseases* 44 (3) 155-67, 2001)

Chung (*Plastic and Reconstructive Surgery* 109 (1) 1-6, 2002)

Atkinson (Chronobiology International 18 (6) 1041-53, 2001).

While several experiments have been conducted, there is no apparent relationship between the results of those experiments, and the claimed invention. The claimed invention encompasses repair of damage to the intestines, treatment of Crohn's disease, treatment of diarrhea, treatment of colitis or sepsis, treatment of hepatitis, treatment of cirrhosis of the liver, and kidney infection, as well as reversal of damage to gut epithelial tissue. There is no evidence that increasing DNA synthesis or even increasing organ weight engenders a method of promoting wound healing, or of successfully treating a patient whose organs have been damaged by disease, surgery or trauma. "Undue experimentation" would be required to practice the claimed invention.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112 second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of promoting "recovery" of an organ. It is unclear as to what the organ is recovering from. The term could potentially encompass recovery from a wound, physical trauma, or a disease. The line between what is encompassed and what is not encompassed is unclear.

✧

Claims 30, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Nakamura (*J. Dairy Sci.* **78** (6) 1253-1257, 1995) in view of Ichikawa (USP 5,071,867) or Masuda (*American Institute of Nutrition* **126**(12) 3063-3068, 1996) in view of Ichikawa ('867) .

Nakamura discloses that peptides obtained from sour milk exhibit antihypertensive activity. Masuda provides a similar teaching. Neither reference discloses that antihypertensive agents promote "recovery" of kidneys. Ichikawa discloses (e.g., col 1, line 21+) that antihypertensive agents promote "recovery" of kidneys. Ichikawa does not disclose administration of milk protein hydrolyzates.

Thus, the nephrologist of ordinary skill would recognize that the milk protein hydrolyzates of Nakamura and of Masuda will be effective to promote recovery of kidneys. The kidney qualifies as a "specific organ".

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gordon (USP 5,166,132).

Gordon teaches that milk protein hydrolyzates can be used to treat skin, which is an organ.

Thus, it would have been obvious to one of ordinary skill that milk protein hydrolyzates will promote "recovery" of at least one particular organ (i.e., skin).

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gordon (USP 5,166,132) in view of Verma (USP 6,645,942).

The teachings of Gordon are indicated above. Gordan does not teach that skin is an organ. Verma discloses (col 4, line 47) that skin is an organ. Verma does not disclose the use of milk protein hydrolyzates to promote recovery of an organ.

Thus, it would have been obvious to one of ordinary skill that milk protein hydrolyzates will promote "recovery" of the skin, and that skin is an organ.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Smith (WO 97/16460).

Smith discloses that a casein hydrolyzate has growth promoting activity. Smith does not

explicitly state that the casein hydrolyzate will promote "recovery of an organ". However, one of ordinary skill would expect that growth of organs will be promoted, those of infants, as well as those of adults who have suffered damage to an organ as a result of disease, injury or surgical procedure.

Thus, the claims are rendered obvious.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Qu, Zhensheng (*Journal of Nutrition* **126**(4) 906-912, 1996) in view of Stalker (USP 5,661,123).

Qu discloses that protein malnutrition is manifest in various ways both biochemically and physiologically; one of those manifestations is suboptimal liver growth. Qu further discloses that the deficiency in liver growth which accompanies protein malnutrition can be reversed by administering proteins, such as casein; in other words, proteins promote "recovery" of the liver from protein malnutrition. Qu does not disclose that hydrolyzed milk proteins can serve as a protein source. Stalker discloses (col 3, line 50) administration of hydrolyzed milk proteins to patients who have "elevated protein requirements". Stalker does not state that hydrolyzed milk proteins will promote "recovery" of organs.

Thus, for the subject who is endeavoring to "recover" from a nutrient deficient state, it would have been obvious to use the hydrolyzed milk proteins of Stalker to reverse the adverse effects on organs resulting from starvation, in accordance with the teachings of

Qu.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446).

Gray discloses (col 2, line 57+) a method of treating patients suffering from burns, and from surgical procedures. The method calls (col 3, line 27) for administration of hydrolyzed milk protein.

Thus, for the subject who is endeavoring to "recover" from damage to an organ from a burn or surgical procedure, the claims are rendered obvious.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446) in view of Van Leeuwen (USP 6,001,878).

Gray discloses (col 2, line 57+) a method of treating patients suffering from burns, and from surgical procedures. The method calls (col 3, line 27) for administration of hydrolyzed milk protein. The reference also suggests (col 3, line 47; col 5, line 56) administration of glutamine in addition to the hydrolyzed milk protein. Gray does not disclose that glutamine will promote recovery of an organ. Van Leeuwen discloses that glutamine will promote recovery of the liver. Van Leeuwen does not disclose administration of hydrolyzed milk proteins.

Thus, for the subject who is endeavoring to "recover" from damage to an organ such

as the liver, the claims are rendered obvious.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446) in view of Panigrahi (USP 5,981,590).

Gray discloses (col 2, line 57+) a method of treating patients suffering from burns, and from surgical procedures. The method calls (col 3, line 27) for administration of hydrolyzed milk protein. The reference also suggests (col 3, line 47; col 5, line 56) administration of glutamine in addition to the hydrolyzed milk protein. Gray does not disclose that glutamine will promote recovery of an organ. Panigrahi discloses that glutamine will promote recovery of the intestines. Panigrahi does not disclose administration of hydrolyzed milk proteins.

Thus, it would have been obvious to combine the glutamine with the hydrolyzed milk protein in order to promote recovery of the intestines.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Boza, Julio (*Journal of Pediatric Gastroenterology and Nutrition* **22**(2) 186-193, 1996).

Boza discloses that the weight and protein content of the jejunum mucosa is reduced following starvation, and that the hydrolase activity of the mucosa also is also reduced in starvation. Boza also discloses that these effects of starvation are reversed following

administration of hydrolyzed milk proteins. Boza does not recite the phrase "promote recovery of an organ". However, Boza does disclose that starvation adversely effects one or more organs, and that these adverse effects are reversed by administration of hydrolyzed milk proteins. Accordingly, it would have been obvious to one of ordinary skill that for the subject who is endeavoring to "recover" from organ damage caused by starvation, administration of hydrolyzed milk proteins will achieve this objective.

✦

(10) Response to argument.

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response, appellants have begun by making a procedural argument, i.e., that the Board of Appeals should reverse the examiner's decision to deny entry of the amendment filed 1/9/06. However, the Board of Appeals generally chooses not to decide which after-final amendments should be entered and which should not. Given that there is agreement between the examiner and the appellants over the wording of the claims at issue, it would seem most appropriate to decide the question of whether the claimed

invention is adequately described by the application as filed, rather than the question of whether appellants should be given additional opportunities to amend the claims.

Turning to the merits of the rejection, appellants have argued that descriptive support can be found on page 9, lines 1-8. The passage on page 9,lines 4-7 is the following:

> In the case of multiple doses, the nutritional formula is conveniently in the form of a convenience food, for example a ready-to-drink beverage. The nutritional formula may also be administered continuously by means of nasogastric tubes or enteral tubes such as jejunum tubes.

It is true that there is descriptive support for administration of a nutritional formula, when administered continuously, by means of nasogastric tubes or enteral tubes. There is also support perhaps for mixing a nutritional formula with a food or beverage and ingesting the resulting mixture. But this does not amount to a general description of "internally administering". Internal administration would also encompass intravenous administration, intraperitoneal administration and subcutaneous administration, none of which are suggested by the instant specification. The term at issue is not described, or even implied by the instant application.

In addition to, and separate from the foregoing, claim 30 recites that the organ for which recovery is to be promoted must be an "internal" organ. There is no descriptive support for this either , and appellants have declined to argue that such support exists.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Appellants have begun by arguing that the specification discloses methods of administering the milk protein hydrolyzates. This particular point is correct.

Appellants have also asserted that "there exists a correlation between rate of protein synthesis and promoting specific organ recovery". However, no evidence is provided in support of this assertion.

Appellants have also argued that the specification does not specifically teach that the milk protein hydrolyzates can be used to treat hepatitis or cirrhosis. Appellants are correct that the disclosure of the application does not specifically assert this; however, the specification does assert (page 8, line 20+) that the milk protein hydrolyzates can be used to treat Crohn's disease, sepsis and diarrhea. One of skill would infer that the specification is asserting that other diseases can be treated by administration of milk protein hydrolyzates. However, whether or not treatment of other diseases is implied by the specification is a secondary issue, and not critical to this ground of rejection.

Next, appellants have pointed out that they have shown that milk protein hydrolyzates can increase the rate of protein synthesis in a rat. While this may be true, there is no

evidence that the skilled physiologist can "predict" success in the treatment of Crohn's disease, sepsis or diarrhea by administering a compound which increases protein synthesis. There is no evidence from the prior art that this may be true, and there is no evidence from the specification that this may be true. Thus, the specification provides no guidance or working examples which would show the skilled artisan how to treat Crohn's disease, sepsis and diarrhea or to otherwise promote "recovery" of an organ, whether that organ is the intestine, the heart, the lungs, the brain, the thymus, the eyes, the liver, the kidney or any other organ. The prior art also does not support such a proposal. Accordingly, "undue experimentation" would be required to practice the claimed invention.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Appellants have argued that the term at issue is definite because there are a few examples of what this encompasses. At the same time, appellants have argued that, while the term ("recovery of an organ") encompasses treatment of Crohn's disease, diarrhea, colitis and sepsis, the term at issue excludes hepatitis, cirrhosis and kidney infection (page 15, Brief).

However, it is not clear how these two interpretations are to be reconciled. One of skill would conclude simply that the term is indefinite.

Appellants have also argued that one can measure "recovery" by measuring protein concentration or RNA concentration. However, neither the specification nor the claims explain how to do this, especially in the case of Crohn's disease, diarrhea, colitis and sepsis.

✦

Claims 30, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Nakamura (*J. Dairy Sci.* **78** (6) 1253-1257, 1995) in view of Ichikawa (USP 5,071,867) or Masuda (*American Institute of Nutrition* **126**(12) 3063-3068, 1996) in view of Ichikawa ('867) .

Appellants have argued that Ichikawa discloses only one specific ACE inhibitor, and that this ACE inhibitor is different from those disclosed by Nakamura and by Masuda. However, this particular argument is not correct. Ichikawa discloses that ACE inhibitors in general exhibit a therapeutic effect on kidneys, especially for those patients suffering from glomerular sclerosis. Ichikawa does not suggest or imply that only certain specific ACE inhibitors are effective in this regard, but instead discloses that therapeutic efficacy is a general property of ACE inhibitors. Thus, one of ordinary skill would expect the ACE inhibitors of Nakamura and of Masuda to be therapeutically effective in the treatment of kidney disorders, and thus, to "promote recovery" of kidneys.

Appellants have also argued that in the absence of hindsight there would be no motivation to combine the teachings of Nakamura with those of Ichikawa, and similarly

there would be no motivation to combine the teachings of Masuda with those of Ichikawa. However, this is not true. For the artisan of ordinary skill endeavoring to treat kidney disease in accordance with the teachings of Ichikawa, it would have been obvious to use an ACE inhibitor in accordance with Nakamura or Masuda.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gordon (USP 5,166,132).

Appellants have argued that Gordon teaches only topical administration, not internal administration. However, Gordon also teaches (e.g., col 6, line 36) that the milk protein hydrolyzates can be used to treat vascular tumors or arthritis. Thus, the medical specialist of ordinary skill would have had motivation to administer the composition subcutaneously or systemically or transdermally. Given that the target site is "internal", the medical specialist of ordinary skill would have had reason to achieve internal administration.

While noting that appellants have traversed the rejection over Gordon ('132) in view of Verma ('942), no further traversal is offered for this ground of rejection, which is imposed over Gordon ('132) only.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gordon (USP 5,166,132) in view of Verma (USP 6,645,942).

Appellants have traversed by arguing that Verma does not disclose administration of milk protein hydrolyzates. This particular point is correct. Appellants have also argued that there is no motivation to combine the teachings of the two references (i.e., Gordon and Verma). In response, Verma is cited because it teaches that skin is an organ. Verma constitutes a form of evidence, or a point of reference. The medical practitioner of ordinary skill would recognize that skin is an organ; but if an artisan endeavoring to practice the invention of Gordon did have any doubt about whether skin is an organ, he would have been motivated to seek out a reference such as Verma to confirm that this is in fact the case. The artisan of ordinary skill does not need to use any of the teachings of Verma in order to practice the claimed invention; one would have had reason to consult Verma merely to confirm that the invention which he is practicing (according to Gordon) does in fact fall within the scope of the instant claims.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Smith (WO 97/16460).

Appellants have traversed by arguing in essence that while Smith does disclose that milk protein hydrolyzates will promote growth of cells, Smith does not disclose that cell growth will result in "recovery" of an organ. However, the artisan of ordinary skill would recognize that if cells of an organ are damaged or destroyed by injury or disease, it would be beneficial to promote growth of the cells of the damaged tissue, as this will help effect repair.

Appellants have also argued that whatever growth promoting effect may be present in the milk protein hydrolyzates of Smith resides in peptides that exhibit growth promoting activity. This may be true, but the claimed invention encompasses administration of milk protein hydrolyzates which exhibit growth promoting activity.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Qu, Zhensheng (*Journal of Nutrition* **126**(4) 906-912, 1996) in view of Stalker (USP 5,661,123).

Before addressing appellants' arguments, it should be noted that item 8 on page 21 of the appeal brief (filed 3/7/06) makes reference to Qu only, whereas the actual ground of rejection is Qu in view of Stalker. That appellants recognized the correct ground of rejection (Qu in view of Stalker) is evident from page 7 of the appeal brief, which lists (as item 9) Qu in view of Stalker.

Appellants have argued that Qu does not teach selecting a milk protein hydrolyzate which will promote recovery of a specific organ. However, this is not true. One of the organs which Qu teaches recovery of is the liver. Appellants have argued that Qu does not teach selecting a particular degree of hydrolysis to target one organ rather than another. While this particular point may be true, the claims do not require such.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over

Gray (USP 5,723,446).

Appellants have argued that Gray does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While appellants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or to a method of targeting one organ over another by varying the degree of hydrolysis. Gray does disclose a method of promoting "recovery" of tissue within a given organ (and hence the organ itself), such as those organs which contain tissue that would be damaged by a burn or by a surgical procedure. The requirements of the claims, as they are presented, are met by the teachings of the reference.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446) in view of Van Leeuwen (USP 6,001,878).

As noted above (the §103 rejection over Gray), appellants have argued that Gray does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While appellants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or to a method of targeting one organ over another by varying the degree of hydrolysis. Gray does disclose a method of promoting "recovery" of tissue within a given organ (and hence the organ itself), such as those organs which contain tissue that would be damaged by a burn or by a surgical procedure.

Appellants have also argued that Van Leeuwen taken by itself does not form the basis for a proper §103 rejection. While this particular point may be true, the point is moot, since the rejection is based on Gray in view of Van Leeuwen. Gray renders obvious the invention even in the absence of Van Leeuwen; the secondary reference when combined with the teachings of Gray render obvious a somewhat different aspect of the claimed invention than Gray taken by itself.

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Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446) in view of Panigrahi (USP 5,981,590).

As noted above (the §103 rejection over Gray), appellants have argued that Gray does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While appellants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or to a method of targeting one organ over another by varying the degree of hydrolysis. Gray does disclose a method of promoting "recovery" of tissue within a given organ (and hence the organ itself), such as those organs which contain tissue that would be damaged by a burn or by a surgical procedure.

Appellants have also argued that Panigrahi taken by itself does not form the basis for a proper §103 rejection. While this particular point may be true, the point is moot, since the rejection is based on Gray in view of Panigrahi. Gray renders obvious the invention

even in the absence of Panigrahi; the secondary reference when combined with the teachings of Gray render obvious a somewhat different aspect of the claimed invention than Gray taken by itself.

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Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Boza, Julio (*Journal of Pediatric Gastroenterology and Nutrition* **22**(2) 186-193, 1996).

Appellants have argued that Boza does not disclose a method of targeting "specific organ recovery". However, this is not true; Boza disclose a method of promoting "recovery" of the intestinal mucosa.

Appellants have also criticized Boza as not arguing that hydrolyzed milk proteins are better than unhydrolyzed milk proteins. This particular point may be true, but Boza does make an affirmative and clearly evident teaching that milk protein hydrolyzates will promote recovery of certain (specific) organs following starvation. The practitioner of the Boza invention would have no doubt about the efficacy of milk protein hydrolyzates in this regard. Appellants have also criticized Boza on the basis that this reference is limited to a teaching of "recovery" following starvation. This particular point may be correct, but there is nothing in the instant claims to exclude the possibility that the "recovery" is from starvation. Appellants have also argued that the reference does not disclose "organ recovery through varying degrees of milk protein hydrolysis".

While this may be true, the claims do not require such; the limitations of the claims are indeed met by the reference.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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